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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,189	10/28/2003	David A. Judd	0942.4180003	2747
26111	7590	01/06/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			WITZ, JEAN C	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/694,189

Applicant(s)

JUDD ET AL.

Examiner

Jean C. Witz

Art Unit

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

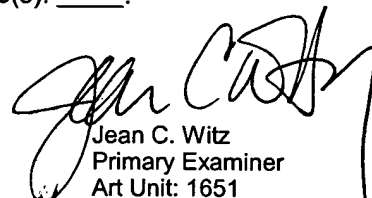
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
Jean C. Witz  
Primary Examiner  
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Continuation of 2. NOTE: added limitation of heparin into the independent claim raises new issues that would require further consideration and/or search.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed December 10, 2004 have been fully considered but they are not persuasive for the reasons set forth below.

Applicants' arguments drawn to the rejection of claims 1, 73-78 and 80-89 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,712,163 to Parenteau et al. are not probative because the arguments are drawn to claims that are not of record in the application due to denial of entry of the amendment filed December 10, 2004.

Applicants' arguments drawn to the rejection of claims 78 and 88-89 under 35 U.S.C. 103 as being obvious over U.S. Patent No. 5,712,163 to Parenteau et al. are not found to be persuasive. Applicants assert that the Examiner has made improper use of official notice of the fact that 10X culture media formulations are conventional. While Applicants are correct that the circumstances should be rare when an application is under final rejection, the MPEP at 2144.03 states that Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)). In *Ahlert*, the court held that the Board properly took judicial notice that "it is old to adjust intensity of a flame in

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accordance with the heat requirement." See also *In re Fox*, 471 F.2d 1405, 1407, 176 USPQ 340, 341 (CCPA 1973) (the court took "judicial notice of the fact that tape recorders commonly erase tape automatically when new audio information' is recorded on a tape which already has a recording on it"). In appropriate circumstances, it might not be unreasonable to take official notice of the fact that it is desirable to make something faster, cheaper, better, or stronger without the specific support of documentary evidence. Furthermore, it might not be unreasonable for the examiner in a first Office action to take official notice of facts by asserting that certain limitations in a dependent claim are old and well known expedients in the art without the support of documentary evidence provided the facts so noticed are of notorious character and serve only to "fill in the gaps" which might exist in the evidentiary showing made by the examiner to support a particular ground of rejection. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); *Ahlert*, 424 F.2d at 1092, 165 USPQ at 421.

The MPEP states that it would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. See also *In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979) ("[W]hen the PTO seeks to rely upon a chemical theory, in

establishing a prima facie case of obviousness, it must provide evidentiary support for the existence and meaning of that theory."); In re Eynde, 480 F.2d 1364, 1370, 178 USPQ 470, 474 (CCPA 1973) ("[W]e reject the notion that judicial or administrative notice may be taken of the state of the art. The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men and are not amenable to the taking of such notice."). It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. Zurko, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained that, "as an administrative tribunal the Board clearly has expertise in the subject matter over which it exercises jurisdiction," it made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." Id. at 1385-86, 59 USPQ2d at 1697. As the court held in Zurko, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. Id. at 1385, 59 USPQ2d at 1697. See also In re Lee, 277 F.3d 1338, 1344-45, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002) (In reversing the Board's decision, the court stated "common knowledge and common sense" on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the

agency's obligation....The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies.").

In the instant case, such notice was not unsupported. The Examiner indicated that *any* tissue culture media catalog would show culture media in both 1X and 10X formulations. The standard for proper official notice without documentary evidence is that the information be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)). The Examiner maintains that documentary evidence was provided; however, in any event, the official notice taken was "capable of such instant and unquestionable demonstration as to defy dispute". A basic word search of the Internet (www.Google™.com) using the terms "1X", "10X", "culture" and "media" provides as the very first hit, the website for Sigma-Aldrich, a conventional supplier of biochemicals and reagents for life science research. At

[http://www.sigmaaldrich.com/Area of Interest/Life Science/Cell Culture/Key Resources/ECACC Handbook/Cell Culture Techniques 6.html](http://www.sigmaaldrich.com/Area_of_Interest/Life_Science/Cell_Culture/Key_Resources/ECACC_Handbook/Cell_Culture_Techniques_6.html), the website states in the

**ECACC Handbook: Fundamental Techniques in Cell Culture . . . A Laboratory Handbook**, that "Whilst all media may be made from the basic ingredients this is time consuming and may predispose to contamination. For convenience most media are available as ready mixed powders or as 10x and 1x liquid media."

As stated in the MPEP, ordinarily, there must be some form of evidence in the record to support an assertion of common knowledge. See *Lee*, 277 F.3d at 1344-45,

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61 USPQ2d at 1434-35 (Fed. Cir. 2002); Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection). In certain older cases, official notice has been taken of a fact that is asserted to be "common knowledge" without specific reliance on documentary evidence where the fact noticed was readily verifiable, such as when other references of record supported the noticed fact, or where there was nothing of record to contradict it. See *In re Soli*, 317 F.2d 941, 945-46, 137 USPQ 797, 800 (CCPA 1963) (accepting the examiner's assertion that the use of "a control is standard procedure throughout the entire field of bacteriology" because it was readily verifiable and disclosed in references of record not cited by the Office); *In re Chevenard*, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943) (accepting the examiner's finding that a brief heating at a higher temperature was the equivalent of a longer heating at a lower temperature where there was nothing in the record to indicate the contrary and where the applicant never demanded that the examiner produce evidence to support his statement). If such notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. The applicant should be presented with the explicit basis on which the examiner regards the matter as subject to official notice and be allowed to challenge the assertion in the next reply after the Office



action in which the common knowledge statement was made. In the instant case, the examiner set forth the reasoning explicitly and in fact, the source documents which were the basis for the reasoning. Other than to assert that the use of official notice was not proper, Applicants have not challenged the assertion on the record with any evidence.

As stated in the MPEP, if Applicants challenge a factual assertion as not properly officially noticed or not properly based upon common knowledge, the Examiner must support the finding with adequate evidence. To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also Chevenard, 139 F.2d at 713, 60 USPQ at 241 ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be inadequate. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). In the instant case, the Examiner has provided explicit evidence to support the official notice, as indicated *supra*.

Finally, if the examiner adds a reference in the next Office action after applicant's rebuttal, and the newly added reference is added only as directly corresponding evidence to support the prior common knowledge finding, and it does not result in a new issue or constitute a new ground of rejection, the Office action may be made final. In the instant case, the reference indicated supra is added only as directly corresponding evidence to support the prior common knowledge finding and does not result in a new issue or constitute a new ground of rejection; therefore, the finality of the prior office action is deemed to be proper and is not withdrawn.

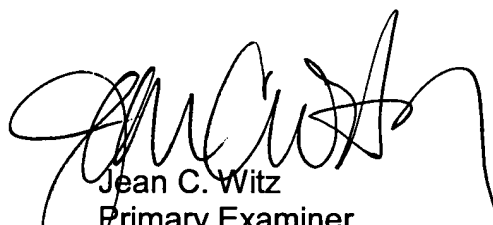
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jean C. Witz  
Primary Examiner  
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